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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/035,218 | 01/04/2002 | Tom Mc Hale | 12013/58801 | 3450 |

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EXAMINER

HO, UYEN T

ART UNIT PAPER NUMBER

3731

DATE MAILED: 05/22/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--|------------------------------------|--|
| Office Action Summary | Application No. 10/035,218 | Applicant(s) HALE ET AL. | |
| | Examiner (Jackie) Tan-Uyen T. Ho | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 1/4/2002 has been considered and placed in the application file.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regard to claim 6, Examiner is unclear whether "the adhesiveness between the coating and the coated medical implant" is increased or decreased as "the number of folds provided in the multi-wing balloon increases." In regard to claim 16, Examiner is unclear whether adhesiveness between the coating and the medical implant or the adhesiveness of the coating of the medical implant to something else.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and/or use the invention. The subject matter "an inverse relationship" between "the number of wings in the multi-wing balloon" and "the softness of the coating of the medical implant" was not described in the specification in such a way to enable one skilled in the art to which it pertains.

6. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for increasing the number of wings in the multi-wing balloon catheter to reduce the torsional forces placed on an implant during expansion, does not reasonably provide enablement for an inverse relationship between the softness of the coating of the medical implant and the number of wings in the multi-wing balloon. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification disclose a coating with less resilient to resist the forces would need to more wings in the multi-wing balloon to reduce the damage of the coating as described in the specification pages 4-5, paragraph 15-19. The specification does not disclose how softer coating or the softness of the coating increased would need fewer wings in multi-wing balloon (an inverse relationship) during the expansion.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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8. Claims 1, 2, 4, 5, 7 and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (6,273,913) in view of Fischell et al. (5,792,172). Wright et al. disclose a balloon-expandable stent including a plurality of cell (fig. 1-3a), the stent being coated with a polymer layer containing therapeutic material (col. 4, line 39 to col. 6, line 11). Although, Wright et al. fails to disclose a balloon catheter having a multi-wing balloon for delivering the stent to a treated site, attention is directed to the Fischell et al. reference which teach a balloon with multifold for multi-wing for delivering a stent including a plurality of cells to a treated site, wherein the number of folds or wings of the balloon is the same as the number of the stent cells for improving the uniformity of stent cell expansion (col. 2, line 25 to col. 3, line 17). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a catheter balloon as disclosed by Fischell et al. for delivering the stent of Wright et al. in order to improve the uniformity of stent cell expansion.

In regard to claim 5, the number of folds provided in the multi-wing balloon inherently affect the coating on the coated medical implant the. The limitation "related to the coating" is considered as the effect of the multi-wing on the coating.

9. Claims 3, 8, 9, (11) and 17-20, are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (6,273,913) in view of Fischell et al. (5,792,172) further in view of Hillstead (5,116,318). Although, the teaching of Wright et al. in view of Fischell et al. fails to disclose a removable elastic membrane encircling the multi-wing balloon before crimping a coated stent onto the multi-wing balloon, attention is directed to the Hillstead reference which teaches an removable elastic membrane encircling the

multi-wing balloon before crimping a coated stent onto the multi-wing balloon in order to provide protection to the balloon and to eliminate a blade-like or wing-like shape in a deflated configuration of the balloon so that to eliminate the possibility of trauma to a blood vessel (col. 2, lines 25-49; col. 3, line 48 col. 5, line 5). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ an elastic membrane as disclosed by Hillstead into the balloon catheter of Fischell et al. for delivering the stent of Wright et al.. in order to provide a better delivery system which eliminates the possibility of trauma to a blood vessel being treated and doing so would meet the method steps of claims 8, 11 and 18-20, as placing the elastic membrane disclosed by Hillstead on the multi-wing balloon of Fischell et al., the surface of the multi-wing balloon would be smooth or polished as the elastic membrane eliminate "blade-like" or "wing-like" and the adhesion between the balloon and the coating would be prevented (the coated stent would only contact the membrane).

10. Claims 8, 10, 18 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (6,273,913) in view of Fischell et al. (5,792,172) further in view of Euteneuer et al. (5,147,302). Although, the teaching of Wright et al. and Fischell et al. do not explicitly disclose the multi-wing balloon being pre-treated such as heating the multi-wing balloon to reduce the multi-wing balloon surface profile, attention is directed to the Euteneuer et al. reference which teaches before placing a tubular sleeve on to a multi-wing balloon, reducing the profile of the multi-wing balloon by partially folding multi-wings of balloon around a core and heating the partially folded balloon to cause the wings to fold or wrap further around a core so that the balloon is

more tightly wrapped than it was prior to the heat treatment in order to install the sleeve over the balloon more easily (col. 3, lines 53-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to pre-treat the multi-wing balloon of Fischell et al. by heating the multi-wing balloon in order to reduce the profile of Fischell et al.'s balloon for facilitating ease of installation of Wright et al.'s stent. Doing so would reduce the adhesion between the balloon and the coated stent and the balloon with smaller profile would reduce the contact between the surface of the balloon and the inner surface of the stent as the stent installed over the balloon.

11. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wright et al. (6,273,913) in view of Fischell et al. (5,792,172) further in view of Hillstead '318 further in view of Trotta et al. (5,290,306) and Jung et al. (5,352,236). Although, the teaching of Wright et al. in view of Fischell et al. further in view of Hillstead fails to disclose an elastic membrane being pre-treated on outside and inside surfaces to reduce the adhesion between the coated stent and the membrane and between the membrane and the balloon, attention is directed the Trotta et al. and Jung et al. references which teach that providing a lubricant on the inner or outer surface of an object in order to provide ease insertion. Jung et al. teach placing a lubricious material on an inner surface of a tubular sleeve in order to permits easy insertion of a wrapped balloon into the sleeve (col. 4, lines 36-44) and Trotta et al. teach placing a lubricant on the surface of a sleeve on a balloon in order to provide easy insertion of the balloon and the balloon may be carry an expandable stent (col. 2, lines 32-44 and col. 3, lines 6-13

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and col. 4, lines 55-59). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ a lubricious material on the inner and outer surface of the elastic membrane in order to provide easy insertion of the stent onto the sleeve or the balloon into the sleeve.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3977 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

(Jackie) Tan-Uyen T. Ho
Patent Examiner
Art Unit 3731
May 18, 2003